MOTION FILED

FEB 1 3 2004

(4)

No. 03-862

IN THE

# Supreme Court of the United States

EXCEL CORPORATION,

*Petitioner,*

*v.*

ESTATE OF BRIANNA L. KRIEFALL, *et al.*,

*Respondents.*

**On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin**

## MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF FOR PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF THE PETITION

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## MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*

Pursuant to Rule 37.2 of the Rules of this Court, the Product Liability Advisory Council, Inc. ("PLAC"), moves for leave to file the accompanying brief as *amicus curiae* in support of the Petition for a writ of *certiorari*. Counsel for Petitioner has consented to the filing of the brief, but counsel for the Individual Respondents withheld consent.

PLAC is a non-profit association with 132 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to improvement and reform of the law governing the liability of product manufacturers in the United States and elsewhere. PLAC's perspective is derived from the experiences of diverse corporate members in industries spanning the manufacturing sector. In addition, several hundred leading product liability defense attorneys across the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 650 briefs as *amicus curiae* in both state and federal courts, including many in this Court, presenting the views of product manufacturers seeking fairness and balance in the application and development of the law affecting product liability. A list of PLAC's corporate members is found in the accompanying appendix.

PLAC believes that the decision of the Wisconsin Court of Appeals cries out for review. At issue is a federal statute, the Federal Meat Inspection Act ("FMIA"), that, among other things, uniformly bans "adulterated" meat from interstate commerce. The responsible federal agency, the United States Department of Agriculture ("USDA"), excludes from the definition of "adulterated" intact meat with certain types of bacteria, such as *E. coli*, on its surface. USDA does not view such meat as adulterated because these naturally occurring bacteria are ubiquitous and because they are easily killed when the meat is cooked before it is eaten.

The court below held USDA's interpretation invalid in Wisconsin. Meat that USDA allows in interstate commerce is now illegally "adulterated" in that state. The court gave USDA's interpretation of "adulterated" no deference because it held that USDA had no authority to construe this part of FMIA. Because one of the nine statutory definitions of "adulterated" expressly referred to administrative discretion, the court held by implication that Congress delegated no authority to USDA to construe the other eight definitions.

PLAC's members manufacture and distribute products for a nationwide market. The Wisconsin ruling threatens uniformity of federal regulation of many kinds of products. Important sections of almost every federal statute regulating product manufacturing could be similarly misconstrued because they likewise have some provisions expressly mentioning administrative discretion, and others that do not.

There is no basis to believe that absence of explicit reference to agency discretion at the level of a statutory subsection reflects congressional intent to deprive federal administrative bodies of discretion. No such intent appears in the legislative history of FMIA. To hold, as the Wisconsin court has here, that such omissions override general grants of administrative discretion and allow states free reign to adopt contrary interpretations of federal statutes would Balkanize the American economy.

PLAC's broad membership allows it to bring a perspective to this case transcending any particular industry or statute. Accordingly, PLAC seeks to submit the accompanying brief to inform the Court of the importance of the issues raised by the Petition, as they affect manufacturers of all federally regulated products, and of the adverse consequences that would flow from leaving those issues unreviewed.

For the foregoing reasons, PLAC's motion for leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of *certiorari* should be granted.

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## INTEREST OF THE *AMICUS CURIAE*[1]

The interest of the *amicus curiae* is described in the accompanying motion for leave to file this brief.[2]

## INTRODUCTION AND SUMMARY OF ARGUMENT

The Court of Appeals of Wisconsin has ruled that Petitioner's meat products were "adulterated" under the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§601-95. The court rejected the position of the United States Department of Agriculture ("USDA"), the expert agency administering FMIA, that the meat was not adulterated. *Estate of Kriefall v. Sizzler USA Franchise, Inc.*, 665 N.W.2d 417 ¶¶20, 33 (Wis. App. 2003) (Pet. App. 19a, 30a).

The court concluded that USDA lacked discretion to interpret "adulterated," as defined in 21 U.S.C. §601(m), to exclude "intact" meat with *E. coli* bacteria on its surface. Ignoring FMIA's general grant of rulemaking authority, 21 U.S.C. §621, the court construed a single reference to "the judgment of the Secretary" in §601(m)(2)(A) to impliedly revoke USDA discretion as to every subsection of §601(m) that did not contain a similar reference (Pet. App. 19a ¶20).

This decision eviscerates FMIA's national meat safety standards. Since commerce in meat transcends state boundaries, a national standard for meat safety is necessary to protect public health. With Wisconsin unilaterally adopting an "adulteration" standard more restrictive and at odds with federal law, regulated meat suppliers such as Petitioner can no longer rely upon federal compliance to satisfy state obligations. While state regulation in this case

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1. Pursuant to Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part and that no person or entity other than *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

2. A list of the members of *amicus curiae* Product Liability Advisory Council, Inc. is in the attached Appendix.

takes the form of common-law tort litigation, the Wisconsin court's holding is not so limited. Should Wisconsin administrative agencies so choose, they may seize or exclude any meat not meeting the court's peculiar definition of "adulterated."

PLAC supports the Petition because the implications of a ruling unilaterally excepting Wisconsin from adherence to USDA's meat adulteration standards are staggering. Uniform federal product regulation has created integrated, national markets for many types of goods. As these statutes are successively amended, provisions added at different times often differ in what they say about administrative delegation.

The Wisconsin decision jeopardizes federal administrative authority at a fundamental level. By flatly denying delegation, it deprives federal administrative decisions of any deference. The assault thus sanctioned on federal regulatory authority acutely threatens regulation of other foods, drugs and cosmetics, since Congress coordinated FMIA's definition of adulteration with the Food, Drug & Cosmetic Act. However, almost every federal statute regulating products will be implicated if this decision is allowed to stand.

## REASONS FOR GRANTING THE WRIT

### I. THE UNIQUE INTERPRETATION OF "ADULTERATED," ADOPTED IN ORDER TO AVOID EXPRESS PREEMPTION OF RESPONDENTS' TORT CLAIMS, THREATENS THE VERY NATIONAL UNIFORMITY THAT FMIA PREEMPTION IS INTENDED TO PRESERVE.

Although the issue in the Petition is not federal preemption as such, the Wisconsin result cannot be understood except in that context. Preemption was the basis of the summary judgment order that the Wisconsin court overturned, and it lurks just beneath the surface throughout that court's opinion.

FMIA has an express preemption clause barring any state from imposing requirements that "are in addition to, or different than" those imposed by USDA. 21 U.S.C. §678. Concurrent federal-state enforcement is permitted if – but only if – a product is "adulterated or misbranded" under the federal USDA standards:

> [A]ny State. . .may. . .exercise concurrent jurisdiction with the Secretary over articles required to be inspected. . .for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded. . . . *Id.*[3]

Congress enacted this cooperative federal/state enforcement scheme to promote uniform regulation of meat. "States would be precluded from imposing additional or different. . . requirements for federally inspected products. Both industry and consumers would benefit from. . .greater uniformity." H.R. Rep. No. 1333 (1968), *reprinted in,* 1968 U.S.C.C.A.N. 3426, 3442. "Federal standards must be

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3. The Wisconsin court "assumed" applicability of §678 to this action (Pet. App. 6a n.3).

required of all meat and meat food products." S. Rep. No. 799 (1967), *reprinted in,* 1967 U.S.C.C.A.N. 2188, 2191.

State enforcement – including state common law actions – survives FMIA express preemption only where meat fails applicable federal standards. In *Jones v. Rath Packing Co.,* 430 U.S. 519 (1977), a state statute rigidly prohibiting weight decrease from moisture loss was preempted by FMIA regulations that allowed "reasonable" variations from labeled weights. Thus, in *Jones,* compliance with the federal standards, *id.* at 528, precluded different, more stringent state-law standards. The Court "conclude[d] that with respect to [the] packaged bacon, [the state provisions] are pre-empted by federal law." *Id.* at 532.

Both before and after *Jones,* other courts in FMIA cases unanimously concluded that USDA standards define the scope of FMIA preemption. Where meat is "adulterated" or "misbranded" for violating USDA requirements, states are not precluded from – and, indeed, are encouraged to – independently enforce the federal standards.[4] Conversely, additional or divergent state standards are preempted where a meat product complies with all relevant federal requirements.[5] Federal preemption under FMIA applies

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4. *Swift & Co. v. Walkley,* 369 F. Supp. 1198, 1199-1201 (S.D.N.Y. 1973) (state enforcement allowed where USDA "acknowledged to [state] officials that it was in error in approving [the] labels"); *People v. Rath Packing Co.,* 149 Cal. Rptr. 431, 443 (Cal. App. 1978) (state may impose additional penalties upon meat not conforming to federal standards).

5. *Grocery Manufacturers of America, Inc. v. Gerace,* 755 F.2d 993, 1003 (2d Cir. 1985) (state "requirements d[id] not comport exactly with the federal specifications, [and t]herefore. . .[we]re preempted"), *aff'd mem.,* 474 U.S. 801 (1985), *cert. denied,* 474 U.S. 820 (1985); *Armour & Co. v. Ball,* 468 F.2d 76, 84 (6th Cir. 1972) ("[i]n its concurrent enforcement a state would not be permitted to prevent the distribution in commerce of any article that 'conforms' to the [federal standard]"), *cert. denied,* 411 U.S. 981 (1973); *Kraft Foods North America, Inc. v. Rockland County Dept. of Weights and Measures,* No. 01 CIV. 6980 (WHP), 2003 WL 554796, at *7 (S.D.N.Y. Feb. 26, 2003) (state-law "inspection practices impermissibly 'differ from' and are 'contrary to'" FMIA requirements); *Cook Family Foods, Ltd. v. Voss,* 781 F. Supp. 1458, 1465-68 (C.D. Cal.

against private tort or contract actions under state law, as well as against state administrative action.[6]

Preemption attaches to USDA pronouncements under FMIA regardless of their administrative pedigree. In *Grocery Manufacturers of America, Inc. v. Gerace,* the Court of Appeals upheld the preemptive effect of USDA's adoption of Food and Drug Administration ("FDA") rules for "imitation" labeling:

> Even if [USDA's action] should be classified as an interpretive rule or a statement of general policy. . . we discern no reason to reject the USDA's longstanding interpretation of [FMIA].

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1991) (state subjective inspection procedures that differed from objective federal standards held preempted by FMIA); *Meat Trade Institute, Inc. v. McLaughlin,* 326 N.Y.S.2d 683, 685 (N.Y.A.D. 1971) (higher city meat standard preempted).

*See also National Broiler Council v. Voss,* 44 F.3d 740, 745 (9th Cir. 1994) ("The provision authorizes states to undertake. . .efforts to enforce *federal* requirements. It does not grant states the authority to enact their own additional requirements") (interpreting identical language of Poultry Products Inspection Act, 21 U.S.C. §467e) (emphasis original); *Northwestern Selecta, Inc. v. Munoz,* 106 F. Supp. 2d 223, 233 (D.P.R. 2000) (preemption under Poultry Products Inspection Act).

6. *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.,* 626 F. Supp. 278, 285-86 (D. Mass.) (consumer fraud claim concerning sub-therapeutic antibiotics preempted), *aff'd without op.,* 802 F.2d 440 (1st Cir. 1986); *Mario's Butcher Shop & Food Center, Inc. v. Armour & Co.,* 574 F. Supp. 653, 656 (N.D. Ill. 1983) ("no liability may be found where the product complies with federal regulations"); *Boulahanis v. Prevo's Family Market, Inc.,* 583 N.W.2d 509, 512 (Mich. App. 1998) ("any state tort action based on a theory that adulterated meat was distributed must therefore be based on standards that are identical to federal standards"), *appeal denied sub nom. Sowerby v. Prevo's Family Market, Inc.,* 591 N.W.2d 38 (Mich. 1999), *cert. denied,* 530 U.S. 1203 (2000); *Kircos v. Holiday Food Center, Inc.,* 477 N.W.2d 130, 131-32 (Mich. App. 1991) (state-law negligence per se action preempted where meat "is not 'adulterated' under the federal act"), *appeal denied,* 487 N.W.2d 412 (Mich. 1992).

755 F.2d 993, 1002 (2d Cir. 1985). When the affected state appealed that decision as of right, this Court summarily affirmed the finding of preemption. *Gerace v. Grocery Manufacturers of America, Inc.*, 474 U.S. 801 (1985).[7]

Under existing law, preemption flowed as a matter of course so long as USDA's determination that Petitioner's meat was not "adulterated" controlled. To avoid preemption required the Wisconsin court to make an extreme and unprecedented ruling – that reference to agency discretion in one subsection of §601(m) impliedly divested USDA of authority to construe every subsection that did not mention discretion.

This ruling has no precedent, and finds no support in FMIA's legislative history. The legislative history of the amendments that added the language at issue states that the "judgment of the Secretary" clause in §601(m)(2)(A) was to "give the Secretary of Agriculture *more* discretion" and "to allow the Secretary. . .to impose *more* stringent restrictions" under that subsection. S. Rep. No. 799 (1967), *reprinted in,* 1967 U.S.C.C.A.N. 2188, 2195 (emphasis added). Nowhere in the legislative history is any suggestion that this amendment was intended to reduce administrative discretion. Where Congress intended to restrict USDA discretion, it said so explicitly. *See id.,* 1967 U.S.C.C.A.N. at 2197 ("[r]emoving the Secretary's discretion" concerning *ante mortem* inspections).

By striking at FMIA itself, the Wisconsin court left a far more extensive tear in the fabric of national uniformity than merely leaving a few non-conforming tort claims unpreempted. The court nullified in Wisconsin USDA's discretionary power to define "adulteration." Anyone in Wisconsin – state agencies as well as private plaintiffs – may now ignore USDA's interpretation. The court's rationale for

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7. The manufacturers sought review of other issues, but their petition for *certiorari* was denied. *Grocery Manufacturers of America, Inc. v. Gerace,* 474 U.S. 820 (1985).

constricting federal administrative discretion is equally applicable to any federal agency or statute.

## II. THE HOLDING THAT USDA WAS IMPLIEDLY DIVESTED OF ITS ADMINISTRATIVE DISCRETION WILL DISRUPT ADMINISTRATION OF OTHER FEDERAL STATUTES.

The Wisconsin court gave no effect to Congress' general delegation of regulatory authority in 21 U.S.C. §621. Solely analyzing 21 U.S.C. §601(m), that court found only "focused" delegation because just one of nine definitions of "adulterated" expressly mentioned USDA discretion (Pet. App. 12a ¶10). For the other eight definitions, the court held that "Congress has itself...defined 'adulterated' without seeking the Secretary's input" (Pet. App. 19a ¶20). Congressional silence rendered USDA "powerless" to interpret those definitions in any way. *Id.*

Many federal statutes regulate products made by PLAC members. Like FMIA, these statutes include multiple definitions or other subsections that inconsistently reference administrative discretion. To demand explicit congressional reaffirmation of such discretion – on a subsection-by-subsection level – would have far reaching effects upon federal regulation of many products.

### A. The Ruling Implicates Federal Regulation Of Food, Drugs, Medical Devices, and Cosmetics.

Besides FMIA, the statute most affected by the Wisconsin court's decision is the Food, Drug & Cosmetic Act, 21 U.S.C. §§301, *et seq.* ("FDCA"). Congress expressly

intended FMIA to track FDCA.[8] In particular, FMIA's "adulteration" and "misbranding" provisions, §§601(m-n), parallel FDCA definitions of those terms for food. *See* 21 U.S.C. §§342-43. Since FMIA's enactment, USDA has continued to adopt FDA standards without significant change. *Grocery Manufacturers,* 755 F.2d at 1002 (discussing "USDA's practice of following the FDA definition").

FDA regulations of prescription medical products would also be affected. If the Wisconsin court's rationale were extended to the equivalent definition of "adulterated" in 21 U.S.C. §351(a),[9] FDA would retroactively lose the authority to interpret for all drugs and medical devices:

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8. The definitions of "adulterated" and "misbranded" in FMIA were expressly "based on the definition[s] of the same term[s] in the Federal Food, Drug, and Cosmetic Act and [are] identical except" for certain changes that Congress specified. S. Rep. No. 799 (1967), *reprinted in,* 1967 U.S.C.C.A.N. at 2194 & 2195. The acts FMIA prohibits are "generally comparable" to acts prohibited by FDCA. *Id.,* at 2199.

9. Section 351(a) states, in pertinent part, that a drug or medical device is "adulterated":

"(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. . .; or (C) if it is a compounded positron emission tomography drug and. . .do[es] not conform to or [is] not operated or administered in conformity with the positron emission tomography compounding standards. . .; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of §379e(a) of this title, or (B) it is a color additive. . .and is unsafe within the meaning of §379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of §360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of §360b of this title."

- what is "filthy, putrid or decomposed," under subsection (1);
- what are "insanitary conditions" and "contaminated with filth," under subsection (2)(A);
- what is "good manufacturing practice" under subsection (2)(B); and
- what are "poisonous or deleterious substance[s]" that cannot be used in containers under subsection (3).

This result would occur because, unlike other parts of §351(a),[10] these subsections neither mention nor reference FDA discretion. Under the Wisconsin court's rationale, FDA could enforce FDCA adulteration standards for color additives and animal feed, but states could override FDA good manufacturing practice for drugs and medical devices.[11]

The adulteration provisions of 21 U.S.C. §351 are only the most directly comparable FDCA analogue. Section 352, pertaining to misbranding, contains eighteen subsections, including five that make no express mention of FDA discretion.[12] The Wisconsin court would thus deny effect to FDA interpretation of these subsections. Similarly, 21 U.S.C. §321 defines numerous substantive terms for the

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10. Subsections (4-6) of this section have cross-references to other FDCA sections that explicitly recognize FDA discretion.

11. *See* 21 C.F.R. Parts 210-11. Statutes are simply not drafted with the precision demanded by the Wisconsin court's focus on subsection-level references to administrative discretion. While §351(a)(2)(B) neither mentions nor references FDA discretion concerning "good manufacturing practice," another section of FDCA expressly grants such discretion — but only for medical devices, not drugs. *See* 21 U.S.C. §360j(f).

12. The subsections of 21 U.S.C. §352 lacking express language are: (a) "False or misleading label," (c) "Prominence of information on label," (i) "Drug; misleading container; imitation; offer for sale under another name," (j) "Health-endangering when used as prescribed," and (s) "Devices subject to performance standards not bearing requisite labeling."

entire statute. Seventeen of these definitions – including such basic terms as "food," "drug," and "cosmetic" – contain no express grant of discretion to FDA.[13] There are numerous other FDCA subsections potentially subject to the same objection that the Wisconsin court interposed here.[14]

## B. The Ruling Implicates Federal Regulation Of Motor Vehicles.

Production of on-road motor vehicles (cars, trucks, motorcycles, *etc.*) is regulated by the National Traffic & Motor Vehicle Safety Act of 1966, 49 U.S.C. §§30101, *et seq.* ("Safety Act"). The Safety Act not only has a general grant of administrative discretion, 49 U.S.C. §30111(a), but also contains many subsection-level references to such discretion.

Such references appear initially in the Safety Act's two sets of definitions. 49 U.S.C. §30102 (a-b). None of the definitions in subsection (a) reference administrative discretion,[15] but subsection (b) ("limited definitions"[16]) contains a provision specifically recognizing such discretion.

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13. *See* 21 U.S.C. §321(f) ("food"); (g)(1) ("drug"); (g)(2) ("counterfeit drug"); (h) ("device"); (i) ("cosmetic"); (j) ("official compendium"); (l) ("immediate container"); (m) ("labeling"); (p) ("new drug"); (r) ("raw agricultural commodity"); (u) ("safe"); (w) ("animal feed"); (y) ("saccharin"); (z) ("infant formula"); (gg) ("processed food"); (ii) ("compounded positron emission tomography drug"); (jj) ("antibiotic drug"). Other definitions do expressly acknowledge FDA discretion. *See* 21 U.S.C. §321(k) ("label"); (q) ("pesticide chemical"); (s) ("food additive"); (t) ("color additive"); (v) ("new animal drug"); (ff) ("dietary supplement").

14. Other FDCA provisions, the subdivisions of which do not uniformly recognize FDA discretion, are: 21 U.S.C. §331 ("prohibited acts"); §333 ("penalties"); §342 ("adulterated food"); and §343 ("misbranded food").

15. These definitions include "defect," "manufacturer," "motor vehicle," and "motor vehicle safety." *See* 49 U.S.C. §§30102(a)(2, 5-6, 8).

16. These definitions include "adequate repair," "first purchaser," "original equipment," and "replacement equipment." 49 U.S.C. §§30102(b)(1)(A-D).

*See* 49 U.S.C. §30102(b)(2). Under the Wisconsin court's reasoning that specific mention of discretion in one subsection excludes discretion elsewhere, the National Highway Traffic Safety Administration ("NHTSA") would lose power to issue binding interpretations of the definitions in §30102(a).

Certain categories of vehicles are excluded from Safety Act regulation by 49 U.S.C. §30112(b). Of nine exceptions, only one specifically references agency discretion.[17] Courts, the legislature, or administrative agencies in Wisconsin could thus ignore NHTSA's reading of the scope of the other eight exceptions and require otherwise exempt vehicles to meet Safety Act standards. Safety Act remedies are also implicated. The statute expressly authorizes NHTSA to promulgate regulations concerning repair or replacement of defective vehicles, 49 U.S.C. §30120(a)(2), but is silent about remedies for defective tires. *Id.* §30120(b).

If the Wisconsin court's opinion stands, federal ability to administer performance and safety standards applicable to more than 10 million motor vehicles sold annually in the United States could be severely degraded.

### C. The Ruling Implicates Federal Regulation Of Consumer Products.

The Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§2051, *et seq.*, charges the federal Consumer Product Safety Commission ("CPSC") with responsibility to set safety standards for a host of products, from cigarette lighters to amusement park rides. Like FMIA, CPSA contains a general grant of administrative discretion. 15 U.S.C. §2056(a). If the Wisconsin court's rationale were applied to CPSA, it would likewise have disruptive effects.

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17. That exception reads: "a motor vehicle the Secretary of Transportation decides. . .is capable of complying with applicable standards under this chapter." 49 U.S.C. §30112(b)(4). This exception applies to imported automobiles. *See id.* §§30141-45.

CPSA §2052 contains definitions applicable to the entire statute. Some of these definitions reference agency discretion or agency rulemaking,[18] but most do not.[19] Under the negative implication rule of the Wisconsin court, CPSC would lose discretion to interpret most of the operative definitions that govern its actions.

Similar situations exist in substantive portions of CPSA. For example, 15 U.S.C. §2064, "Substantial product hazards" expressly references discretionary CPSC orders in subsections (b-d), (e)(2) and (g) – but not in subsections (a) (defining "substantial product hazard") and (e)(1) (authorizing reimbursement orders). If the Wisconsin decision extends to CPSA, CPSC cannot enforce its interpretations of the very hazards it is charged with preventing.[20]

The decision in this case uniquely threatens the entire range of federal uniform nationwide product safety standards. For this reason, the Court should grant the Petition.

## III. THE WISCONSIN COURT'S REFUSAL TO GIVE ANY DEFERENCE TO USDA'S ACTION CONFLICTS WITH THIS COURT'S DECISIONS.

Almost as stunning as denying USDA discretion to interpret FMIA §601(m) is the Wisconsin court's next step. The court put its own gloss on §601(m), giving USDA

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18. Definitions expressly referencing the administrative authority or rules include: §2052(a)(1) (defining "consumer product"); and (a)(2) (defining "consumer product safety rule").

19. Definitions in §2052(a) lacking reference to administrative discretion include: (3) ("risk of injury"); (4) ("manufacturer"); (5) ("distributor"); (6) ("retailer"); (7) ("private labler"); (8) ("manufactured"); (11) ("distribute in commerce"); and (12) ("commerce").

20. Similar implied divestiture of administrative discretion could occur under the rationale of the Wisconsin court with respect to the Federal Insecticide, Fungicide, Rodenticide Act. *See* 7 U.S.C. §§136 ("definitions"); 136j ("unlawful acts").

decisions no deference. On the same administrative record, *see* (Pet. App. 21a-27a ¶¶23-26), the court struck a radically different balance than USDA. It essentially disregarded the factor USDA found most compelling – that ordinary cooking routinely eliminates health risks from *E. coli* and other bacteria.[21] Instead, the court recast USDA's "goal" of "zero tolerance" for visible digestive matter into "zero tolerance" for bacteria and interpreted §601(m) to require bacteria be "reduc[ed] to an undetectable level," regardless of other considerations. *See* (Pet. at 10 n.2) (Pet. App. 26a, 31a ¶¶25, 34).

This cavalier disregard of USDA decisions and creation of a novel, Wisconsin-specific definition of "adulterated" should be barred by the deference accorded administrative action. Deference is particularly needed where, as here, a state court reviews federal action. The Wisconsin court's holding is contrary to well-settled deference principles under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and subsequent cases.

### A. This Court's Decisions Require Deference Be Given To The USDA Action In This Case.

When an agency interprets its own organic statute, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction." *Chevron*, 467 U.S. at 843. *Chevron* analysis is thus bifold: (1) does the statute speak to the precise question, and (2) if not, is the agency's interpretation permissible. *Id.* at 842-43; *Food & Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). Here, FMIA's multiple definitions of "adulterated" are unclear as to bacteria generally and

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21. *E.g., Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143, 145-49 (W.D. Tex. 1994); 67 Fed. Reg. 62,325, 62,326 (Oct. 7, 2002), 64 Fed. Reg. 2803, 2804 (Jan. 19, 1999); 60 Fed. Reg. 6774, 6799 (Feb. 3, 1995); *see also American Public Health Ass'n v. Butz*, 511 F.2d 331, 332 (D.C. Cir. 1974) (cooking kills salmonella; no need for microscopic examination).

silent on both *E. coli* and "intact" meat. Therefore, the Wisconsin court should not have ignored USDA's decision.

USDA's decision, while an interpretive rule rather than a formal regulation, appeared three times in the Federal Register, and was judicially reviewed. *See, supra,* at n.21. *Chevron* deference is not premised upon notice and comment rulemaking. *Edelman v. Lynchburg College,* 535 U.S. 106, 114 (2002) (*Chevron* "does not necessarily require . . .express notice-and-comment rulemaking"); *United States v. Mead Corp.,* 533 U.S. 218, 230-31 (2001) ("reasons for *Chevron* deference even when no such administrative formality was required and none was afforded"); *Young v. Community Nutrition Institute,* 476 U.S. 974, 981-83 (1986) (informally adopted FDA "action levels" given *Chevron* deference ). Earlier this Term, the Court gave a "measure of respect" to agency guidance memoranda that had not even been published in the Federal Register. *Alaska Dep't of Environmental Conservation v. EPA,* ___ U.S. ___, 124 S. Ct. 983, 1001 (2004) ("*ADEC*"). Agency action qualifies for *Chevron* deference "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Mead Corp.,* 533 U.S. at 226-27.

USDA's interpretation deserves *Chevron* deference under *ADEC* and *Mead.* Congress delegated authority to USDA in 21 U.S.C. §621. USDA actions under its delegated authority carry force of law, as evidenced by sanctions for noncompliance. *See,* 21 U.S.C. §§676 (criminal penalties); 673 (seizure/condemnation). Under this Court's precedents, the Wisconsin court was obligated to defer to USDA's permissible interpretation of "adulterated."

### B. Did Congress Address The Precise Question?

Deciding if Congress specifically addressed the question requires review of the entire statute – not, as here, isolated subsections. *Brown & Williamson,* 529 U.S. at 132. "[W]ords

of a statute must be read in their context and with a view to their place in the overall statutory scheme," with "all parts" fitting, if possible "into an harmonious whole." *Id.* at 132-33 (citations omitted). *See also Brown v. Gardner,* 513 U.S. 115, 118 (1994) ("[a]mbiguity is a creature not of definitional possibilities but of statutory context"). Implicit in statutory ambiguity is delegation to the agency to fill such gaps, and courts are not to substitute their readings for reasonable agency interpretations. *Chevron,* 467 U.S. at 844.

Congress did not address in FMIA when live bacteria would make fresh meat "adulterated." Definitions of "adulterated" are purposely vague, keeping them dynamic. Inclusion of all adulterating circumstances in FMIA would doom it to obsolescence. USDA now considers as adulterants substances that were not so thought – or were entirely unknown[22] – in 1967 when §601(m) was amended.

That the Wisconsin court's holding is so profoundly in conflict with USDA's construction of "adulterated" itself indicates statutory ambiguity. *Smiley v. Citibank (South Dakota), N. A.,* 517 U.S. 735, 739 (1996) ("difficult indeed" not to find ambiguity given "the conflict that has prompted us to take this case") (footnote omitted).[23] Further, by considering only the discretion mentioned in 21 U.S.C. §601(m)(2)(A), to the exclusion of FMIA's general delegation

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22. *E. Coli* 0157:H7 was first discovered in 1975 and not identified as a human pathogen until 1982. *See* < http://vm.cfsan.fda.gov/~mow/fdacook.html > (visited Feb. 10, 2004) (FDA Medical Bulletin (June 1993)). Similarly, only in 1992 were misshapen proteins called prions confirmed as causing "mad cow" disease (bovine spongiform encephalopathy). *See* < http://www.nobel.se/medicine/laureates/1997/press.html > (visited Feb. 6, 2004) (official announcement of award of 1997 Nobel Prize in Medicine to Dr. Stanley B. Prusiner for discovery of prions).

23. The holding here also conflicts with *American Public Health Ass'n v. Butz,* 511 F.2d at 334 (salmonella not an "adulterant" under §601(m)); and *Texas Food Industry Ass'n,* 870 F. Supp. at 145-49 (USDA properly declared *E. coli* an "adulterant").

to USDA,[24] the court violated this Court's command to treat the statute as a whole. *Brown & Williamson,* 529 U.S. at 132-33. The express congressional delegation in §621 is an excellent indicator that USDA's decision here deserves deference under *Chevron. Mead Corp.,* 533 U.S. at 231.

### C. Was USDA's Interpretation Permissible?

Courts must defer to agency interpretations that reflect permissible statutory constructions. *Chevron,* 467 U.S. at 843. Having improperly held FMIA's definitions of "adulterated" to be unambiguous, the Wisconsin court never addressed the permissibility of USDA's decision that "intact" meat with only surface *E. coli* was not adulterated.

Congress "underst[ands] that [statutory] ambiguity would be resolved, first and foremost, by the agency, and desire[s] the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows." *Smiley,* 517 U.S. at 740-41 (citation omitted). Deference is required: (1) because "responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," *Chevron,* 467 U.S. at 866; and (2) due to "the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated." *Brown & Williamson,* 529 U.S. at 132 (citation omitted). An agency construction need not be the only possible outcome – only "sufficiently rational. . .to preclude a court from substituting its judgment for that of [the agency]." *Young,* 476 U.S. at 981 (citations omitted).

USDA's recognition that surface *E. coli* die when cooked, 64 Fed. Reg. at 2804, justifies its conclusion that

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24. "[S]aid Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter." 21 U.S.C. §621.

the meat at issue is not "adulterated."[25] Meat is "ordinarily" cooked before it is eaten, so surface bacteria no longer "render it injurious to health." 21 U.S.C. §601(m)(1). By contrast, the Wisconsin court's decision is unfairly retroactive. Not only is the "goal" of "zero tolerance" (Pet. App. 26a, 31a) misconstrued, *see, supra,* at 13, it came from a policy statement issued in October, 2002[26] – more than two years after the July 2000 incident alleged in the complaint.

## IV. INVALIDATION OF USDA'S DISCRETIONARY STATUTORY INTERPRETATION IMPLICATES FMIA'S CONSTITUTIONALITY.

If USDA cannot clarify broad statutory terms such as "poisonous," "deleterious," "filthy," "putrid," and "insanitary," §601(m) may become unconstitutionally vague. This Court has held statutes "void for vagueness if [their] prohibitions are not clearly defined." *Grayned v. Rockford,* 408 U.S. 104, 108 (1972). First, the law must "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited." *Id.* Second, to prevent arbitrary or discriminatory enforcement, "laws must provide explicit standards for those who apply them." *Id.* Vague laws

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25. This conclusion followed exhaustive fact finding by USDA's Food Safety & Inspection Service ("FSIS"). FSIS is a sponsor of the National Advisory Committee on Microbiological Criteria for Foods, the entity Congress has charged with conducting scientific studies and surveillance concerning food. *See* 68 Fed. Reg. 46,569, 46,569-70 (Aug. 6, 2003) (describing Committee). Federal Register entries concerning the *E. coli* policies at issue detail the dozens of epidemiological studies and other scientific resources FSIS utilized. *See* 67 Fed. Reg. at 62,326-27 & nn.3-19; 65 Fed. Reg. 6881, 6883 (Feb. 11, 2000); 64 Fed. Reg. at 2804-05; 60 Fed. Reg. at 6781-84, *see also id.* at 6834-37, 6852-53, 6854-55 (220 listed references, 20 mentioning the *E. coli* bacterium in their titles).

26. Pet. App. 26a, 31a (citing 67 Fed. Reg. at 62,329).

impermissibly give "basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis." *Id.* at 109.[27]

The effect of the Wisconsin court's decision is to wipe away USDA administrative interpretations that import necessary structure to FMIA. The court's strait-jacketed interpretation admits neither nuance nor practicality. Meat suppliers could now be criminally sanctioned for "adulterated" meat, based on nothing more than the all-encompassing FMIA definition. With no limiting principle, a Wisconsin declaration of *per se* adulteration because all potentially harmful bacteria must be "undetectable" (Pet. App. 26a ¶26) in tests not required by any statute or regulation, would be the sort of "*ad hoc* and subjective" ruling condemned as unconstitutionally vague in *Grayned, supra.*[28]

FMIA's adulteration definitions track FDCA and other federal statutes, against which void-for-vagueness challenges have failed in light of ample administrative guidance. "The Secretary's interpretive regulations. . .concretize the statutory language [and] eliminate the possibility of vagueness."[29] Conversely, vagueness challenges to such definitions have succeeded where "the language of the

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27. *See also, e.g., Smith v. Goguen,* 415 U.S. 566, 575-76 (1974); *Papachristou v. City of Jacksonville,* 405 U.S. 156, 162 (1972).

28. As Petitioner points out (Pet. at 8), all raw meat naturally contains bacteria, and bacteria such as *E. coli* and salmonella can hurt people eating improperly prepared meat. The Wisconsin court's holding that such bacteria, regardless of circumstances, are "deleterious substance[s that] may render [meat] injurious to health" under §601(m)(1) potentially declares all raw meat "adulterated."

29. *United States v. Articles of Drug Labeled Colchicine,* 442 F. Supp. 1236, 1241 (S.D.N.Y. 1978) (citations omitted); *see, e.g., United States v. Sullivan,* 332 U.S. 689, 694 (1948); *United States v. Jamieson-McKames Pharmaceuticals, Inc.,* 651 F.2d 532, 545 n.24 (8th Cir. 1981); *United States v. Article of Drug Labeled "White Quadrisect,"* 484 F.2d 748, 749 (7th Cir. 1973); *United States v. Bel-Mar Laboratories, Inc.,* 284 F.Supp. 875, 883 (E.D.N.Y. 1968).

statute, [is] unclarified by appropriate regulations of the Secretary."[30] Wisconsin is no longer bound by USDA's clarifying regulations.

It is irresponsible to expose broad federal statutes essential to public health to vagueness charges by divesting administrative agencies of long-standing discretion to interpret and clarify their language. Vagueness challenges arise in criminal cases. They give comfort to serious violators and place responsible businesses that comply with existing regulations at competitive disadvantage. This Court should not permit such unnecessary disruption of federal regulation.

## CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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February 13, 2004

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30. *United States v. Fabro, Inc.*, 206 F. Supp. 523, 526 (M.D. Ga. 1962); *see also, United States v. 2,116 Boxes of Boned Beef*, 516 F. Supp. 321, 344-45 (D. Kan. 1981), *aff'd*, 726 F.2d 1481 (10th Cir.), *cert. denied*, 469 U.S. 825 (1984).

# APPENDIX

## APPENDIX

## PRODUCT LIABILITY ADVISORY COUNCIL, INC. CORPORATE MEMBERS

3M
Altec Industries
Altria Corporate Services, Inc.
American Household, Inc.
American Suzuki Motor Corporation
Amgen Inc.
Andersen Corporation
Anheuser-Busch Companies
Appleton Papers, Inc.
Astec Industries
Aventis Pharmaceuticals, Inc.
BASF Corporation
Baxter International, Inc.
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone/Firestone, Inc.
Briggs & Stratton Corporation
Bristol-Myers Squibb Company
Brown and Williamson Tobacco
Brown-Forman Corporation
CARQUEST Corporation
Caterpillar Inc.
CCA Industries, Inc.
Chevron Corporation
Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation
DaimlerChrysler Corporation
Dana Corporation
Deere & Company
Delphi Corporation
Dorel Juvenile Group, Inc.
Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Federal Signal Corporation
FMC Corporation
Ford Motor Company
Freightliner LLC
General Electric Company
General Motors Corporation
Georgia-Pacific Corporation
GlaxoSmithKline
GLOCK, Inc.
Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Guidant Corporation

Harley-Davidson Motor Company
Harsco Corporation
Heil Company
Honda North America, Inc.
Hyundai Motor America
ICON Health & Fitness, Inc.
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Lincoln Electric Company
Masco Corporation
Mazda (North America), Inc.
McNeilus Truck and Manufacturing, Inc.
Medtronic, Inc.
Mercedes-Benz of North America, Inc.
Michelin North America, Inc.
Miller Brewing Company
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc
Panasonic
Pentair, Inc.
Pfizer Inc.
Pharmacia Corporation
Polaris Industries, Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Procter & Gamble Company
Purdue Pharma L.P.
Raymond Corporation
Raytheon Aircraft Company
Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Schering Corporation
Schindler Elevator Corporation
SCM Group USA Inc.
Sears, Roebuck and Co.
Shell Oil Company
Sherwin-Williams Company
Smith & Nephew, Inc.
Snap-on Incorporated
Sofamor Danek, Medtronic Inc.
Solutia Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
Thomas Built Buses, Inc.
TK Holdings
Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive US LLC
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Water Bonnet Manufacturing, Inc.
Whirlpool Corporation
Wilbur-Ellis Company
Wyeth
Yamaha Motor Corporation, U.S.A.
Zimmer, Inc.